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10/574,108

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2006-0446A

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EXAMINER

HABTE, KAHSA Y

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



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AUG 13 2009

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In re Application of :  
Herold et al. :  
Serial No.: 10/574,108 : Decision on Petition  
Filed: 31 March 2006 :  
Attorney Docket No.: 2006-0446A :

This letter is in response to the petition filed under 37 C.F.R. § 1.144 filed on July 27, 2009 requesting reconsideration of the restriction and/or lack of unity requirement.

**BACKGROUND**

This application was filed as a national stage application under 35 USC 371 and as such, is eligible for unity of invention practice.

On 19 September 2008, the examiner required an election of species amongst the various definitions of R1 in claim 1. The examiner used the criteria and form paragraph for US restriction practice by stating the inventions were independent and distinct and a search and examination would be burdensome.

On 20 October 2008, applicants elected, with traverse, Group (A) and the compound of Example 5 on page 26 of the specification. Applicants traversed the requirement by pointing to the PCT search report and its indication of novelty.

On 5 December 2008, the examiner mailed to applicants a non-final Office action. The examiner addressed the traversal and made the requirements final. The examiner required applicants to amend the claims according to the elected species, with regard to variables R1 and Q. Claims 11-22 were provisionally rejected under nonstatutory double patenting. Claim 20 was rejected under 35 USC 112, 1<sup>st</sup> paragraph for scope of enablement. Claims 21-22 were rejected under 35 USC 112, second paragraph, as being indefinite.

On 6 April 2009, applicants filed a response to the Office action.

On 27 April 2009, the examiner mailed to applicants a final Office action. The examiner again required applicants to amend the claims to the definition of R1 = [1,4] benzoxanine or file a petition for the restriction requirement. Claims 11-21 were provisionally rejected under nonstatutory double patenting.

On 27 July 2009, applicant submitted the petition currently under review.

## DISCUSSION

The petition and file history have been carefully considered.

I. Concerning the restriction requirement: it is noted that the original election of species requirement was improperly set forth using the criteria of independence, distinction and burden, which is not applicable to a national stage filing of a PCT application in compliance with 35 USC 371.

In order to require an election of species amongst embodiments of a Markush claim in a national stage filing of a PCT application, the examiner should have followed the guidance provided by the International Search and Preliminary Examination Guidelines published January 2004, relevant parts of which are provided below:

The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B)(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(B)(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.

In paragraph (B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

In this instance, the examiner has not established whether the species are of a similar nature. Should the examiner wish to maintain the election of species requirement, the next Office action should contain appropriate reasons for insisting upon an election of species requirement, which rely upon ISPE Guidelines and PCT Rules.

## II. Concerning the extent of examination required for a Markush claim:

35 USC 121 permits the Office to require an election of species for prosecution on the merits, to which the claims shall be restricted if no generic claim is finally held to be allowable. Maintaining a restriction requirement amongst species would be predicated upon a rejection under 35 101, 102, 103 or 112 1<sup>st</sup> paragraph. In this instance, because the only pending rejection is provisional non-statutory double patenting rejection, the correct practice would have been to extent search and examination to a second to subsequent species..

## III. Concerning the objection to the claims for containing non-elected subject matter:

The claims are written using Markush format. Applicants are entitled to retain non-elected species recited in the alternative of a Markush type claim, for consideration under the examination practice for Markush claims, set forth in MPEP 803.02. For this reason, the objection to the claims for reciting non-elected species is improper.

## IV. Concerning the provisional non-statutory double patenting rejection:

It is noted that the examiner has included claim 18 in the obviousness type double patenting rejections. Claim 18 is limited to the elected species. Some of the pending claims in the related applications re also limited to species. If upon reconsideration, the examiner takes the position that the elected species is considered obvious over non-elected species, then the unity of invention requirement amongst such species should be withdrawn.

It is noted that the only outstanding rejection in the Office action mailed 27 April 2009 is a non-statutory double patenting rejection. If the provisional double patenting rejection is the only rejection remaining, then the guidance in MPEP 804 applies:

The “provisional” double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that “provisional” double patenting rejection is the only rejection remaining in at least one of the applications.

### Nonstatutory Double Patenting Rejections

If a “provisional” nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later- filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal

disclaimer must be required in the later-filed application before the rejection can be withdrawn.

## DECISION

The petition is **GRANTED** for the reasons set forth above.

The objection of Claims 11-21 for reciting non-elected subject matter is withdrawn.

The election of species requirement has been withdrawn, pending re-instatement if appropriate reasoning using PCT Rules can be set forth by examiner in the next Office action.

The Office action of February 13, 2009 is withdrawn as incomplete, because there is no rejection under 35 USC 101, 102, 103 or 112 over the elected species, nor is there any rejection under 35 USC 101, 102, 103 or 112 over a second or subsequent embodiment in Markush claim, nor are claims encompassing the elected invention indicated as in condition for allowance. Moreover, the obviousness type double patenting rejections do not refer to the claims, as pending, in the related cases.

**The application will be forwarded to the examiner for preparation of a supplemental non-final Office action consistent with this decision, in which the claims 11-21 will be examined, per guidance in MPEP 803.02. The obviousness type double patenting rejections will be reconsidered in view of the claims as pending in each application. Should any elected and non-elected species be considered obvious one over the other, as evidenced by any obviousness type double patenting rejections, then the requirement to elect a single species should be withdrawn. Should the provisional double patenting rejection be the only remaining rejection, the examiner should follow the guidance in MPEP 804.**

Should there be any questions about this decision, please contact Quality Assurance Specialist Julie Burke, by letter addressed to Director, Technology Center 1600, at the address listed above, or by telephone at 571-272-1600 or by facsimile sent to the general Office facsimile number, 571-273-8300.



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